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In the Supreme Court of the United States

OCTOBER TERM, 1968

No. 1019

CHAS. PFIZER & CO., INC., PETITIONER

v.

FEDERAL TRADE COMMISSION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE FEDERAL TRADE COMMISSION IN OPPOSITION

OPINIONS BELOW AND JURISDICTION

The opinions below and the basis for this Court's jurisdiction are set forth in the petition (Pet. 1–2) and appendix thereto (App. 1–375).[1]

QUESTIONS PRESENTED

1. Whether the court of appeals correctly held that the Commission's finding that Pfizer improperly suppressed material information in obtaining the tetra-

[1] App. refers to the appendix to the petition for certiorari. R. refers to volumes I through XXII of the joint appendix and S.R. to the single-volume, joint supplemental appendix filed in the court of appeals.

cycline patent from the United States Patent Office was supported by substantial and admissible evidence.

2. Whether the court of appeals correctly upheld the Commission's order for compulsory licensing of the tetracycline patent.

STATUTE INVOLVED

Section 5(a)(1) of the Federal Trade Commission Act, 38 Stat. 719, as amended by 52 Stat. 111 and 66 Stat. 632 (15 U.S.C. 45(a)(1)), provides:

> Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are hereby declared unlawful.

STATEMENT

Petitioner ("Pfizer") seeks review of the unanimous judgment of the court of appeals affirming a unanimous Federal Trade Commission decision which found that Pfizer had made misrepresentations to, and withheld material information from, the United States Patent Office, resulting in the issuance to Pfizer of a patent on the antibiotic "tetracycline". The Commission held that Pfizer's subsequent exploitation of the monopoly rights under that patent violated Section 5 of the Federal Trade Commission Act.[2]

1. THE BROAD-SPECTRUM ANTIBIOTIC INDUSTRY

Tetracycline is one of several so-called "broad spectrum" antibiotics which were discovered and developed after the advent of penicillin and streptomycin

[2] The Commission also found, and the court of appeals affirmed, that American Cyanamid Company ("Cyanamid") aided Pfizer in securing the tetracycline patent by withholding material information. Cyanamid did not petition for certiorari.

and which are considered to be effective against a wide range of bacteria (R. X, 5003a). When the Commission's complaint issued there were four broad-spectrum antibiotics on the market: chlortetracycline, oxytetracycline, chloramphenicol, and tetracycline (R. IV, 1997a). Cyanamid owned the patent on chlortetracycline (which expired in 1966) and manufactured and sold this product, under the trade name "Aureomycin," between 1948 and 1966 (R. IV, 1997a; V, 2271a). Pfizer held the patent on oxytetracycline ("Terramycin") from 1950 to 1967 and was its sole manufacturer and seller (R. IV, 1997a; V, 2059a). Parke, Davis & Company was the patentee and only producer and seller of chloramphenicol ("Chloromycetin") from 1949 to 1966 (R. IV, 1997a; V, 2271a).

Tetracycline was first introduced on the market by Cyanamid in November 1953 under the trade name "Achromycin." Pfizer soon followed with its tetracycline product sold under the name "Tetracyn." Thereafter, Bristol-Myers Company ("Bristol"), the former Squibb Division of Olin Mathieson Chemical Company ("Squibb"), and The Upjohn Company ("Upjohn") placed tetracycline on the market under various other brand names (R. XII, 6550a, 6811a; XIII, 6842a, 6935a, 7007a).

2. THE INTERFERENCE PROCEEDINGS BEFORE THE PATENT OFFICE

Although Cyanamid was the first company to make and sell tetracycline, Pfizer was the first of several firms to file a patent application on tetracycline with the Patent Office. The application (Conover applica-

tion), filed on October 23, 1952, claimed as novel both the product and the process by which it was produced. That process involved the removal of a chlorine atom from chlortetracycline (Aureomycin) by mild catalytic hydrogenation. (R. IV, 1613a–1630a, 1640a; X, 5018a–5033a, 5144–5149a.)[3]

Subsequent to the filing of the Conover (tetracycline) application, Pfizer became involved in two interference proceedings instituted by the Patent Office to resolve the question of priority of invention between various applicants. The first interference was terminated early in 1954 by a settlement between Pfizer and Cyanamid that encompassed concession by Cyanamid to Pfizer of priority of invention and a cross-license agreement. Under its terms Pfizer was licensed to make and use chlortetracycline for conversion into tetracycline and in return Cyanamid was licensed under any tetracycline patent Pfizer might receive. Cyanamid also agreed to sell tetracycline in bulk to Pfizer until the latter could manufacture its own product in sufficient quantities. (R. V, 2297a–2299a; XII, 6306a–6339a.)

Thereafter the Patent Office declared a second interference involving Pfizer, Cyanamid and Bristol, on the product "tetracycline hydrochloride," on the basis of a Bristol affidavit which raised the possibility that tetracycline hydrochloride (a salt) was patently distinct from the base (non-salt) form of

[3] It was later discovered that tetracycline could also be made directly by the fermentation of microorganisms—the method by which Aureomycin, and most other antibiotics, are presently manufactured (R. IV, 1778a–1781a; VIII, 3851a–3855a; X, 5160a, 5256a; XI, 5923).

tetracycline (R. X, 5329a–5355a, 5356a, 5361a). However, before proof was taken, Patent Examiner Lidoff ruled on October 14, 1954, that neither tetracycline nor its hydrochloride was legally patentable because it appeared that tetracycline was not in fact a novel compound. He speculated that tetracycline had always been inherently coproduced in the prior-art fermentation processes that were described in Cyanamid's Aureomycin patents (the "Duggar" and "Niedercorn" patents). He stated (R. XI, 5843a–5844a):

> * * * The interference count is unpatentable over the disclosures of Duggar US 2,482,055, Sept. 13, 1949 and Niedercorn US 2,609,329, Sept. 2, 1952, and the interference is dissolved. Duggar and Niedercorn each produce an antibiotic, disclosed as "Aureomycin" by a fermentation process employing *Streptomyces aureofaciens* and mutants thereof. The antibiotic is identified as an antibiotic by assay against bacteria. It appears from the disclosure of Minieri et al. (a party to this interference in an application available to all the parties) that tetracycline is *also* produced in such a fermentation process and that larger proportions thereof are produced when the amount of chloride in the fermentation medium is low (see page 1, lines 5 to 20 and lines 24 to 28 and pages 12, 16, 17, 18 and 19 of Minieri et al. S.N. 383,637). Minieri et al. clearly and specifically disclose that the microorganism used to prepare *tetracycline* belongs to the Duggar et al. US 2,482,055 species and that "the characteristics are identical with those exhibited by a known culture of *S. aureofaciens*". While

neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate, and disclose, that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes (see *In re Lieser,* 1947 C.D. 447; and *Allen et al.* v. *Coe,* 1943 C.D. 55). It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the count (see *Parke Davis* v. *Mulford,* 189 F. 95 and *In re Kebrich,* 96 USPQ 411). [Emphasis in original.]

3. PFIZER'S MISREPRESENTATION TO, AND WITHHOLDING OF MATERIAL INFORMATION FROM, THE PATENT OFFICE

Immediately upon learning of this ruling, Pfizer initiated steps to overcome the patent examiner's assumption that tetracycline was coproduced in the Duggar and Niedercorn processes (R. XI, 6043a–6046a, 6100a–6101a, 6122a, 6148a–6149a, 6212a, 6215a). Two Pfizer scientists, Dr. Tanner and Dr. Bogert, conducted tests pursuant to these processes and found: (1) that it was difficult to achieve *any* significant antibiotic potency of either chlortetracycline or tetracycline in fermentations using the particular microorganism that Cyanamid had placed on public deposit as part of its disclosure requirements when it obtained its Aureomycin (chlortetracycline) patents;[4]

[4] It was later revealed during the administrative hearings that Cyanamid had not actually used this weak microorganism in any of the processes which the patents claimed had significant antibiotic potency (R. III, 896a–897a; VI, 2659a–2664a).

and (2) that of the 44 fermentation examples described in the Niedercorn patent and the example disclosed in the Duggar patent, only one (Example 1 of the Niedercorn patent) yielded a broth clearly sufficient in potency for purposes of testing whether it contained any tetracycline; and this broth did in fact show approximately five percent tetracycline to be present (R. III, 1433a; IV, 1803a–1808a, 1857a–1861a; XI, 6046a–6053a, 6056a–6057a, 6150a–6152a, 6155a–6156a, 6160a, 6213a–6214a, 6216a–6218a).

Subsequently, Pfizer's patent representatives attempted unsuccessfully to persuade the patent examiner to withdraw the rejection of the tetracycline product claims, arguing that his position was not legally sound and that, in any event, there was no evidence to support his assumption of inherent coproduction of tetracycline with chlortetracycline in prior-art Aureomycin processes. Mr. Lidoff declined to withdraw the rejection unless Pfizer could demonstrate through tests that the assumption of coproduction was incorrect (R. X, 5053a–5056a). Tests were then run by Dr. Tanner and Dr. Bogert, but in contrast to their earlier tests, only two fermentations were prepared—the one detailed in the Duggar patent and the other described in Example 28 of the Niedercorn patent (R. IV, 1782–1783a). They did *not* duplicate the Niedercorn Example 1 broth from which they had earlier recovered fractions which contained approximately five percent tetracycline. Instead they obtained, as they knew they would from their previous tests, broths too low in antibiotic potency to test for possible coproduction of

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tetracycline (R. III, 1008a–1016a; XX, 10467a–10468a.)

On December 8, 1954, Pfizer filed papers with the Patent Office (including affidavits of Drs. Tanner and Bogert) claiming that tests performed on two "representative" fermentations selected from the numerous examples set forth in the prior-art patents had failed to substantiate the examiner's assumption of coproduction (R. IV, 1688a–1689a; X, 5052a–5072a; XI, 6074a–6077a).[5] Pfizer did not reveal, however, either that the test broths were of an extremely low potency, or that the two scientists had earlier found that coproduction actually did occur in the one example of the prior-art patents that yielded sufficient broth potency. Also omitted was any mention of the high pH level during the first 6½ hours of one of the fermentations, although the applicable patent had specified a much lower pH level for optimum results (R. X, 5009a, col. 3, lines 16–22; IV, 1817a–1822; XI, 6027a–6028a, 6061a–6062a).

The patent examiner requested further explanation of one of the tetracycline identification tests referred to in Dr. Bogart's affidavit, and asked Pfizer to explain why no further efforts had been made to separate and recover tetracycline from certain amorphous

[5] In addition to the two affidavits, the papers filed by Pfizer included what in patent practice is known as "Remarks" or "Amendments" which summarized the interviews of Pfizer's patent representatives with Mr. Lidoff in late November and early December 1954 (R. X, 5053a–5059a). This summary was drafted by Mr. Hutz, the attorney principally responsible for the prosecution of the Conover (tetracycline) application on behalf of Pfizer (S.R. 314s, 345s, 351s).

materials taken from the test broths (R. IV, 1692a; X, 5074a–5075a). In response, Pfizer filed a supplemental affidavit of Dr. Bogert providing details of the identification test and stating that the amorphous materials were too small and too weak to permit recovery of any tetracycline that conceivably could be present in them. According to Dr. Bogert, there was no indication whatever of the presence of tetracycline (R. IV, 1847a; X, 5076a–5079a). On the basis of these representations, Patent Examiner Lidoff withdrew his rejection of Pfizer's application, and on January 11, 1955, Pfizer was granted U.S. Patent No. 2,699,054 on tetracycline (R. X, 5015a–5017a).

4. INFRINGEMENT SUITS AND SUBSEQUENT LICENSING UNDER THE TETRACYCLINE PATENT

While the second interference was pending, Bristol commenced the manufacture and sale of tetracycline (R. XII, 6811a), and agreed to supply Squibb and Upjohn in bulk for resale to the drug trade (R. XII, 6439a–6451a, 6501a–6505a). Within hours following the issuance of the tetracycline patent Pfizer filed infringement suits against Bristol, Squibb, and Upjohn. In their answers and countersuits, the three firms denied that they were infringing any valid patent claims on tetracycline, alleging, *inter alia,* that the claims were unenforceable because of Pfizer's "unclean hands" arising from misrepresentations of fact to the Patent Office. In December 1955, after the defendants had taken lengthy depositions of Pfizer scientists and other personnel (R. XI, 5965a–6201a), the suits were settled. Pfizer licensed Bristol

to manufacture and sell, and Squibb and Upjohn to sell tetracycline (R. V, 2093a–2109a). No other companies were thereafter licensed by Pfizer to make or sell tetracycline, and the prices for which the five companies sold tetracycline remained substantially identical and uniform. (R. XII, 6550a–6552a, 6811a; XIII, 6812a, 6842a–6843a, 6935a, 7007a.)

5. PROCEEDINGS BELOW

The original administrative proceeding. The complaint, issued on July 28, 1958, alleged basically two violations of Section 5 of the Federal Trade Commission Act. Pfizer and Cyanamid were charged with unlawful enforcement for their benefit of the monopoly rights under the tetracycline patent, alleged to have been secured through false and misleading representations to, and withholding of material information from, the Patent Office. Pfizer, Cyanamid, Bristol, Squibb and Upjohn were charged with conspiring to maintain high prices in the sale of tetracycline. (R. I, 11a–24a.)

The hearing examiner dismissed the complaint for failure of proof (R. I, 99a–368a). The Commission reversed, finding the allegations fully supported by the evidence. Following further arguments on the question of relief, it ordered Pfizer to license its tetracycline patent to any domestic applicant on a 2½ percent royalty basis and to provide licensees with certain technical know-how. Cyanamid was similarly directed to license its two Aureomycin patents for the production of tetracycline. All five companies were prohibited from entering into price-fixing arrange-

ments and each was directed to redetermine its tetracycline prices. (R. II, 486a–754a.)

The first appellate review. On June 16, 1966, the court of appeals remanded the case to the Commission for a new hearing on all issues without the participation of Chairman Dixon, whom it held disqualified by reason of his prior exposure to the subject matter as chief counsel of a Senate subcommittee (App. A153–A163). For the assistance of the Commission on remand, the court upheld the Commission's jurisdiction to inquire into Pfizer's and Cyanamid's conduct before the Patent Office and its power to order compulsory licensing of patents found to have been obtained by misrepresentation or withholding of material information (App. A163–A171). The court further held that the Commission's decision on the patent aspect of the case was insufficiently supported by the evidence (App. A171–A186). Specifically, the court concluded that since the hearing examiner and the Commission had drawn opposite inferences and conclusions regarding the knowledge and intent of Patent Examiner Lidoff, the record could be clarified only by his testimony concerning facts known only to him (App. A182–A186).

The administrative proceedings on remand. Mr. Lidoff was then called as a witness by complaint counsel and testified and was cross-examined at length.[6] He stated that, had he been informed by

[6] At the time of the original administrative proceeding, the Commission's complaint counsel unsuccessfully endeavored to secure the testimony of Patent Examiner Lidoff. The Patent Office then declined to make him available because of a long-standing policy of prohibiting patent examiners from testifying

Pfizer of the presence of five percent coproduction in a prior-art broth, he would not have allowed the patent (S.R. 218s–219s, 221s–222s). He also testified that, had Cyanamid informed him during the second interference that Aureomycin samples contained tetracycline, this would have been an additional ground for rejecting Pfizer's product claims (S.R. 243s–245s), and that deviations in Pfizer's test broths from the specifications of the prior-art patents were material and should have been disclosed (S.R. 225s–227s, 301s–305s). The hearing examiner found that the Lidoff testimony was reliable, probative and fully corroborated by the Patent Office record, and that both Pfizer and Cyanamid were entirely aware of Mr. Lidoff's interest in inherent coproduction of tetracycline (S.R. 78s–80s, 82s–107s). Hence, in his initial decision, he sustained the charges that Pfizer and Cyanamid had withheld material information from the Patent Office (S.R. 117s–118s).

The Commission, with Chairman Dixon not participating, unanimously adopted the hearing examiner's findings and conclusions on the patent issue as supplemented by its own opinion which denied various objections by Pfizer and Cyanamid to the initial decision and to the admissability of Lidoff's testimony (App. A284–A335). The Commission required Pfizer to grant to any domestic applicant a nonexclusive license to make and sell tetracycline under the tetracycline pat-

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in cases involving the validity of patents. However, following the first appellate review and "[a]fter a full and careful consideration of the unusual, exceptional and extraordinary circumstances surrounding [this] case," the Commissioner of Patents authorized Mr. Lidoff to testify. (S.R. 211s–212s, 394s–395s.)

ent. Cynamid was similarly ordered to grant licenses under its Niedercorn (Aureomycin) patent to the extent that any such applicant may utilize patented Aureomycin in processes in the manufacture of tetracycline. (App. A334–335.)[7]

The second appellate review. The court of appeals upheld the Commission's decision and order on remand as fully supported by the record as supplemented by Patent Examiner Lidoff's testimony (App. A342–A362).

ARGUMENT

The principal issue in this case is a factual one: whether there is substantial evidence in the lengthy and complex record to support the Commission's finding that the tetracycline patent was obtained by suppression of material information. This finding is the basis for the Commission's conclusion that the subsequent trade-restraining use of the improperly obtained patent violated Section 5 of the Federal Trade Commission Act. After having scrutinized the case twice, the court of appeals was satisfied that the Commission's determination that Pfizer acted unlawfully was amply supported by the record as supplemented by Mr. Lidoff's testimony. There is no reason for further review.

1. In its first opinion, the court of appeals, after a painstaking review of the record as it then stood, concluded that the ultimate questions of whether the patent examiner received all the information he

[7] By a divided vote of two to two the Commission dismissed that portion of the complaint charging all five respondents with price-fixing (App. A332–A334).

sought, and whether he was deceived into granting the patent, could not be answered without the testimony of Lidoff as to his knowledge, attitudes and intentions at that time (App. A184). The court propounded a list of subsidiary questions, as to which sharp disagreement was evident between the Commission and its hearing examiner, and which the court considered material to resolution of the ultimate questions (App. A182–A184). On remand Lidoff testified fully on the disputed issues, and was expressly asked the questions the court had listed as crucial (App. A367–A373). The same panel of the court of appeals, reviewing the record a second time, this time as supplemented by the Lidoff testimony, concluded that (App. A345):

> Much of the previous uncertainty in the record is eliminated by the testimony of H.J. Lidoff * * *.
>
> Lidoff's testimony contradicts the inferences and findings of fact of Hearing Examiner Robert L. Piper in his initial decision and supports the initial findings of the Commission as well as the findings on remand.

In short, the court below concluded that the deficiencies in the record it had found on its first review had been cured, and that the Commission's decision was supported by substantial evidence.

Although it was petitioner that initially insisted that Lidoff's testimony was essential to resolution of the patent issue (App. A184–185; A359),[8] it now

[8] Pfizer, having first contended that the issue of unfair and inequitable conduct before the Patent Office could not be resolved without Lidoff's testimony, should not be heard to claim

argues that such testimony should have been neither admitted nor relied upon because Lidoff lacked independent recollection of events occurring in 1954 and 1955 (Pet. 8, 13–14). Of course, Lidoff's failure to recollect conversations which took place more than a decade earlier is hardly surprising; and both the Commission (App. A306–A307) and the court (App. A359–A360) took full account of it. His testimony did, however, demonstrate: firm recall of the views he held (at the time the Conover application was pending before him) on the patentability of a chemical compound such as tetracycline (S.R. 216s, 219s–220s, 221s–223s, 238s, 240s, 241s–242s, 271s–272s, 282s–283s, 285s); thorough knowledge of the then existing Patent Office practices, procedures and policies (S.R. 216s, 221s, 223s–224s, 229s, 240s–241s, 244s, 249s, 260–261s, 273s, 298s–299s, 303s); and complete consistency of his

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now that admission of this testimony offends the rule of *Morgan* v. *United States*, 313 U.S. 409, which disapproves of subjecting judicial or quasi-judicial officials to probing cross-examination by parties who strive to overturn decisions made by the officials (Pet. 11). In any event that principle is not apposite here. Lidoff's testimony was sought, not for the purpose of second-guessing his administrative discretion, but to ascertain the materiality of representations made and information withheld by petitioner in seeking to influence his decision. It is surely not the law that one charged with securing favorable action by inequitable conduct or fraud is immune from testimony by the official concerned as to the materiality of information given or withheld from him. The factors influencing the decision of the official are peculiarly within his knowledge; he is the best witness as to the materiality of information concealed, and his testimony is thus relevant to test the regularity of the administrative proceedings. *United States* v. *Aleli*, 170 F. 2d 18, 20 (C.A. 3); cf. *Singer Sewing Machine Co.* v. *National Labor Relations Board*, 329 F. 2d 200, 206–208 (C.A. 4).

written rejection of the Conover application in November 1954 (pp. 5–6, *supra*) with his testimony in September 1966 (S.R. 215s–217s, 218s–220's, 238s, 258s–259s, 283s). In these circumstances, the court of appeals correctly ruled that the failure to recall the details of the interviews (which occurred more than eleven years prior to Mr. Lidoff's testimony) was a matter going not to admissibility but to credibility, an issue upon which courts defer to the judgments of the hearing examiner and the Commission (App. A359–A360; see *Federal Trade Commission* v. *Cement Institute,* 333 U.S. 683, 705–706). The hearing examiner, observing Lidoff as a witness, credited his testimony. The Commission and the court of appeals, after careful consideration and rejection of petitioner's objections, concluded that Pfizer did not meet the standard of "highest degree of candor and good faith" required of applicants before the Patent Office. See *Kingsland* v. *Dorsey,* 338 U.S. 318, 319; *Precision Instrument Manufacturing Co.* v. *Automotive Maintenance Machine Co.,* 324 U.S. 806, 818. The subsequent exploitation of a patent secured by this misconduct was correctly found to violate Section 5. There is no occasion for a reexamination by this Court of the substantial evidence on which the finding of misconduct, concurred in by the Commission and the court below, rests.

2. This court has repeatedly held that the Commission has wide discretion to frame its orders so as to assure prompt and complete rectification of the violations it has found. See, *e.g., Federal Trade Commission* v. *National Lead Co.,* 352 U.S. 419, 428–429; *Atlantic Refining Co.* v. *Federal Trade Commission,* 381 U.S.

357, 376. The Commission's judgment will not be set aside unless the remedy chosen lacks any reasonable relationship to the unlawful practices it seeks to correct. *Siegel Co.* v. *Federal Trade Commission,* 327 U.S. 608, 612–613; *Federal Trade Commission* v. *Ruberoid Co.,* 343 U.S. 470, 473; *Federal Trade Commission* v. *Colgate-Palmolive Co.,* 380 U.S. 374, 394–395.

These principles are fully applicable to the Commission's remedy in this case—compulsory patent licensing—and support the court's sustaining of the agency's order. It is immaterial that the statute does not expressly authorize the Commission to order compulsory patent licensing. *Federal Trade Commission* v. *Eastman Kodak Co.,* 274 U.S. 619, 623–625, on which petitioner relies in this regard (Pet. 17), was specifically rejected in *Federal Trade Commission* v. *Dean Foods Co.,* 384 U.S. 597, 606, n. 4. *Eastman Kodak* reflects an earlier, now discredited, view of a restricted remedial discretion of administrative agencies. Modern authority makes clear that agency remedial discretion is analogous to that of a court of equity. See *Pan American World Airways, Inc.* v. *United States,* 371 U.S. 296, 312–313, nn. 17–18; *Gilbertville Trucking Co.* v. *United States,* 371 U.S. 115, 129–131.

As the court of appeals observed (App. A170–A171), compulsory licensing of patents is recognized as a permissible remedy in antitrust cases. *E.g., Hartford-Empire Co.* v. *United States,* 323 U.S. 386. Its employment here is, therefore, peculiarly appropriate, since exploitation of a patent procured by fraud may

violate the Sherman Act as well as the Federal Trade Commission Act. See *Walker Process Equipment, Inc.* v. *Food Machinery & Chemical Corp.*, 382 U.S. 172. In the circumstances of this case, the compulsory licensing order was reasonably designed to restore and stimulate competition in the tetracycline market—indeed, it was obviously the minimum remedy required to reduce the economic effect of the violation.

CONCLUSION

For the reasons stated, the petition for writ of certiorari should be denied.

Respectfully submitted.

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MARCH 1969.

U. S. GOVERNMENT PRINTING OFFICE: 1969